

Phillip Wm. Lear  
Lear & Lear PLLC  
808 E South Temple Street  
Salt Lake City, UT 84102  
Telephone: (801) 538-5000  
Facsimile:(801) 538-5001  
Email: [phillip.lear@learlaw.com](mailto:phillip.lear@learlaw.com)  
Local Attorney for Linda P. Smith

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF UTAH  
CENTRAL DIVISION

LINDA P. SMITH,

*Plaintiff*

v.

XAVIER BECERRA, in his capacity  
as the Secretary of the United States  
Department of Health and Human  
Services,

*Defendant*

Case No. 1:21-cv-00047-HCN-DBP

PLAINTIFF'S REPLY IN SUPPORT  
OF MOTION FOR SUMMARY  
JUDGMENT AND TO VACATE

JURY TRIAL DEMANDED

Judge Howard Nielson, Jr.  
Magistrate Judge Dustin B. Pead

Mrs. Smith's motion should be granted. This Court should declare CMS 1682-R illegally issued and vacate it. Further, this Court should reverse the Secretary's denial of Mrs. Smith's claims and remand with instructions to provide coverage.

## **I. DISCUSSION**

### **A. Reply Re: Statement of Undisputed Material Facts**

The Secretary did not attempt to rebut the facts set forth in Plaintiff's motion. Where the Secretary did include them in his papers, the Secretary did so simply to contend, falsely, that they were not facts and not material.

With respect to materiality, the facts set forth in Plaintiff's papers showed that, prior to the issuance of the Ruling, ALJs were operating under one standard and, under that standard, were finding Medicare coverage for CGMs. Conversely, after CMS 1682-R issued, ALJs and the MAC were bound by the Ruling and required to deny coverage for anything not meeting CMS 1682-R's construction of "primarily and customarily used to serve a medical purpose." Under this new and different standard, ALJs and the MAC were compelled to deny Medicare coverage for CGMs that would have been covered under the prior standard. This is material because 42 U.S.C. § 1395hh(a)(2) requires notice and comment for anything that "establishes or changes a substantive legal standard."

The Secretary's contention that statements regarding the actual contents of documents or events are not "facts" is not worthy of a response.

**A. The Secretary's "New" Answer**

As indicated in Plaintiff's motion to amend the schedule (Dkt. #25), when motion papers are due less than 21 days after the Answer, the Secretary's representative's tactic is to file an "Answer" filled with non-responses and/or bad faith denials for the purpose of delay, evasion, and harassment. The Secretary's representative affixes his signature to these documents. Accordingly, the opposing party is forced to file briefs without the basic notice of what is disputed required by both the Federal Rules and decisions from the Supreme Court (*e.g.*, *Iqbal/Twombly*). Having improperly achieved this tactical advantage, after the opposing party files its briefs, the Secretary files a new "Answer" picking and choosing which paragraphs of the Complaint to actually respond to depending on how the opposing party treated the issues.

That improper conduct is exactly what occurred in this case. This is another example of bad faith litigation conduct, which one court already found the Secretary's representative engages in. Moreover, even the new "Answer" includes frivolous responses/bad faith denials. For example, Paragraph 2 of the Complaint alleged that this Court had jurisdiction over this case. *See* Dkt. #2 at ¶ 2. In the new "Answer", the Secretary first contended that no response to the allegation of

jurisdiction was required before closing with a general denial. *See* Dkt. #30. The idea that no response is required to an allegation of jurisdiction is frivolous or, taken alternatively, there is no good faith basis for a denial of jurisdiction. Plaintiff addresses this conduct here so that it does not go unremarked and because Plaintiff anticipates that it may be the subject of future briefing.

## **B. The Secretary's Arguments**

As set forth above, the Secretary did not dispute any of the relevant facts or legal conclusions (*e.g.*, that CMS 1682-R was not published in the FEDERAL REGISTER prior to its taking effects, that CMS 1682-R was subject to the notice and comment requirements of 42 U.S.C. § 1395hh, etc.).

Instead, the Secretary's arguments appear to be limited to: 1) the notion that this Court lacks the power to vacate a Ruling issued illegally by the Secretary; and 2) assuming that the Ruling issued illegally, the idea that this Court should remand this matter for further process on Mrs. Smith's claims before the Secretary rather than grant coverage. *Opp.* at 17. The first argument is wrong and the second should be rejected.

### **1. This Court Has the Power to Vacate Rulings Illegally Issued By the Secretary**

At its core, the Secretary's assertion that this Court lacks the power to vacate Rulings (*i.e.*, purported regulations) issued illegally by the Secretary is foreclosed by, at least, the Supreme Court's decision in *Bowen v. Michigan Academy of Family*

*Physicians*, 476 U.S. 667 (1986). There, a group of physicians challenged the validity of a regulation used in determining the amount of benefits. Just like Mrs. Smith's suit in this case, the physician's suit was brought under 42 U.S.C. § 1395ff(b) through 42 U.S.C. § 405(g). The Supreme Court affirmed the district court's invalidation of the challenged regulation and rejected the Secretary's argument that the court lacked the power/jurisdiction to take that step. *Id.* at 680 ("Challenges to the validity of the Secretary's instructions and regulations are cognizable in courts of law. ... We ordinarily presume that Congress intends the executive to obey its statutory commands and, accordingly, that it expects the courts to grant relief when an executive agency violates such a command.") (cleaned up).

Indeed, pursuant to 5 U.S.C. § 706(2), this Court may "hold unlawful and set aside agency action." Here, the "agency action" being challenged is BOTH the illegal issuance of CMS 1682-R and the denial of Mrs. Smith's claims. The Secretary's charge that this Court's power is limited to "affirming, modifying, or reversing" the Secretary's decision denying Mrs. Smith's claims flies in the face of the Supreme Court's instruction in *Bowen* that "the mere fact that some acts are made reviewable should not suffice to support an implication of exclusion as to others." *Bowen*, 476 U.S. at 674. Further, as noted in Plaintiff's moving papers, *Hospice of New Mexico, LLC. v. Sebelius*, 435 Fed.App'x. 749, 754 (10<sup>th</sup> Cir. 2011) and the

other cases cited indicate that when a regulation is invalid and cannot be severed, then the proper course is to vacate the entire regulation. Mot. at 10.

This Court has the power to vacate the Secretary's illegally issued Ruling and, because the Secretary has not even offered a defense of the Ruling itself, this Court should vacate CMS 1682-R as issued without notice and comment in violation of 42 U.S.C. § 1395hh. Indeed, anything less than vacatur would not be consistent with the mandate of the statute that "no rule" promulgated without notice and comment "shall take effect."

## **2. There Should Be No Remand**

In the event that this Court finds that CMS 1682-R issued illegally, rather than granting coverage of Mrs. Smith's claims, the Secretary asks for a remand for further process. Opp. at 17. A remand of this case for additional process would be pointless and wasteful.

Pursuant to 42 U.S.C. § 405(g), this Court may affirm, modify, or reverse the Secretary's denial of Mrs. Smith's claims, "with or without remanding the cause for a rehearing." In the present case, the only basis for denial of Mrs. Smith's claims was that her CGM was not "primarily and customarily used to serve a medical purpose" as defined in CMS 1682-R. With the invalidation of that illegally issued Ruling, there is no basis to deny Mrs. Smith's claims. Indeed, as set forth in Mrs. Smith's co-pending motion for summary judgement, the Secretary is collaterally

estopped from denying that Mrs. Smith’s CGM is “primarily and customarily used to serve a medical purpose.” Further, even if the Secretary was not collaterally estopped, no rational person could ever conclude otherwise and, as the *Olsen* Court found, the allegation that a CGM is not “primarily and customarily used to serve a medical purpose” is frivolous and in bad faith. Thus, a remand for further process would be pointless and wasteful because any decision that Mrs. Smith’s CGM did not meet this requirement would be both barred and frivolous.

## II. CONCLUSION

For the reasons set forth above, this Court should declare that CMS 1682-R issued illegally and vacate it. Further, this Court should find that Mrs. Smith’s CGM claims are covered “durable medical equipment” and, pursuant to 42 U.S.C. § 405(g) (fourth sentence), the Court should remand this matter to the Secretary with instructions to cover the claims at issue.

Dated: October 5, 2021

Respectfully submitted,

PARRISH LAW OFFICES

/s/ James C. Pistorino

James C. Pistorino

*Attorneys for Plaintiffs*

LEAR & LEAR PLLC

/s/ Phillip Wm. Lear  
Phillip Wm. Lear  
Attorneys for Plaintiff